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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,646	12/07/2001	Peter W. Bringmann	BERLX 87	7678

7590 11/25/2005
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EXAMINER

SAUD, CHRISTINE J

ART UNIT PAPER NUMBER

1647

DATE MAILED: 11/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/005,646

Applicant(s)

BRINGMANN ET AL.

Examiner

Christine J. Saoud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-41 and 69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-41 and 69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 10 October 2005 has been entered.

Status of Claims

Applicant should note that the clean copy of the claims in the Appendix is not in compliance with CFR 1.121(c) which requires "the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered)". Claims 37, 38 and 69 do not have any identifiers indicating the current status. Correction is required in the next response. Failure to comply with this rule may result in a holding of a non-responsive reply.

Claim Rejections - 35 USC § 103

Claims 36-41 and 69 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Webster (Multiple Sclerosis 3: 113-120, 1997) in view of Nakamura et al. (Glia 28: 53-65, 1999) for the reasons set forth in the previous Office action(s).

Applicant begins by arguing the previous rejection of claim 40 for lack of written description. However, this rejection was withdrawn in response to the after final amendment filed 15 August 2005. As indicated in the Advisory action, mailed 08 September 2005, the amendment made to claim 40 obviated the rejection.

Applicant argues the rejection of claims 36-41 and 69 under 35 U.S.C. 103(a) at page 2 of the response. Applicant's arguments have been fully considered but are not persuasive to overcome the rejection of the claims under 35 USC 103(a). Applicant argues that Webster in view of Nakamura et al. do not motivate one skilled in the art to use FGF-9 for treatment of MS and the references of Webster and Nakamura et al. do not teach or suggest the administration of FGF-9 for the treatment of MS. Applicant argues that the "speculative statements of Webster and/or Nakamura are not enabled and supported by objective evidence in the references for any specific growth factors for the treatment of any specific disease, and more particularly, are not enabled or supported by objective evidence for the use of FGF9 for the treatment of MS".

Applicant's arguments have been fully considered, but are not deemed persuasive. Webster was cited for the teachings that growth factors, including FGFs, are involved in the proliferation, differentiation and survival of cells in the oligodendroglial lineage, and that oligodendroglia are the cells that form and maintain myelin sheaths. Webster teaches that administration of growth factors could increase proliferation of progenitor oligodendrocytes, enhance their differentiation, upregulate synthesis of myelin constituents and promote myelin regeneration in the adult CNS, which would be

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beneficial for treatment of MS. Therefore, Webster teaches that growth factors which have particular biological activities on the cells that form and maintain myelin sheaths would be beneficial for treatment of MS. Webster does not teach FGF-9 administration for the treatment of MS. Nakamura et al. teach a number of biological activities for FGF-9, including the ability to promote proliferation of primary cortical astrocytes, oligodendrocyte type 2 astrocyte progenitor cells, fibroblasts and neuron-like PC-12 cells. Based on the teaching of Webster that growth factors with particular activities could be used to treat MS, and the teachings of Nakamura et al. that FGF-9 has biological activities consistent with those which would be deemed useful for treatment of MS as identified by Webster, it would have been *prima facie* obvious to use FGF-9 for the treatment of MS.

Applicant asserts that Webster and Nakamura et al. are speculative, and therefore, the combination is merely an invitation to try. However, the instant specification provides no more than the combination of Webster and Nakamura et al. The instant specification does not administer FGF-9 for the treatment of MS. The instant specification bases the claimed invention on the ability of FGF-9 to stimulate PC 12 cells, which are cells obtained from rat adrenal gland. Therefore, based on the biological activity of FGF-9 on "cells of neuronal origin", Applicant asserts that FGF-9 would be useful for treatment of MS. This is exactly what is taught in the prior art, so it is not clear how the prior art is not enabling but the instant application is enabling. The art teaches the mechanism of MS and what biological activities should be stimulated for treatment, suggests that growth factors would be beneficial and provides a growth factor

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which has the biological activities indicated as being necessary for treatment of MS.

The instant specification provides no more than what is provided in the prior art, and therefore, there is insufficient evidence to suggest that the prior art is not enabling and conclude that the specification is enabling. If the prior art is not enabling, than neither is the instant specification.

Applicant again references page 114 of Webster as pointing away from the claimed invention. However, as stated previously, the entire disclosure of Webster must be considered and single statements should not be taken out of context. Webster clearly points out the limitations of the experimental models being used to assess the activities of growth factors *in vivo* and *in vitro* as well as on cells of human origin versus rodent origin. But the general teaching of Webster is the process of MS, what cells are involved, and which biological activities of growth factors would be necessary and desired for use in treatment of MS (see Figure 1). Therefore, it is concluded that Webster does not teach away from using growth factors for the treatment of MS, but does provide useful guidance in selecting a useful growth factor for treatment of MS.

Applicant asserts that the teaching of Webster and Nakamura et al. are conflicting and inconsistent as to the activity of FGF-9 in rodents. This assertion is not based on any facts of record. Webster does not disclose the biological activity of FGF-9, and therefore, cannot provide conflicting data with Nakamura et al.

The rejection of the instant claims is maintained for the reasons of record.

Conclusion

No claim is allowed.

This is a continuation of applicant's earlier Application No. 10/005,646. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on mttr, 8:00-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**CHRISTINE J. SAOUD
PRIMARY EXAMINER**

Christine J. Saoud